MEDTECH & PHARMA
PLATFORM

Medtech & Pharma Platform Association 2021 Annual Conference

'Achieving agility to foster innovation and bring value to patients'

Conference report

The Medtech & Pharma Platform Association (MPP) 8th Annual Conference (MPP2021), dedicated to 'Achieving agility to foster innovation and bring value to patients', took place on 21 October 2021. Focusing on products combining medicinal product, medical device and software component (thereafter referred to as combined products), the conference aimed to foster synergies between the pharma, medtech and ICT sectors and exchanges on combined products development and frameworks. The virtual setting enabled once more a broad participation from an international audience, with more than 460 registered participants from industry, patient organizations, academia, regulators, Notified Bodies and national competent authorities.

- *The conference enabled cross-sectoral exchange between the medtech, pharma and ICT sectors.*
- *The framework for combined products must be responsive to technological developments and foster regulatory convergence.*
- *The digitalization of the healthcare sector brings opportunities for combined products whilst challenging the existing framework.*
- *A certain degree of standardization is needed in the definition and regulatory processes for combined products.*
- *Cooperation between all stakeholders and the early involvement of patients is essential for the development and timely market access of combined products.*

The conference was opened by the MPP President, Shayesteh Fürst-Ladani (SFL), Kaspar Sutter (Canton of Basel-Stadt) and the MPP2021 Program Committee Chair, Dorit Prüfer (Roche). In her keynote address, Jacqueline Huh (Stop TB Partnership) drew lessons from her experience in the fight against tuberculosis for global health and healthcare. She underlined that while the pandemic brought to light the vulnerability, inequity and unsustainability of certain aspects of many healthcare systems, it also provided a window of opportunity for change. She advocated for a multi-disease approach to health and to access and delivery of healthcare services, based on equity, inclusiveness and gender responsiveness. During the discussion with the audience, Jacqueline Huh called for enhanced collaboration between the public and private sectors and emphasized the need to break the current silo approach to healthcare as well as to involve patients' perspective early on in the development process.

Salvatore Scalzo (European Commission), Khair ElZarrad (US FDA), Anthony Humphreys (EMA), Birka Lehmann (University of Bonn), Jonathan Sutch (Team-NB) and Jack Turner (UK MHRA) shared global perspectives on the future framework for combined products during a panel discussion moderated by the MPP President.

Shayesteh Fürst-Ladani provided an overview of the challenges posed by the coexistence of different regulatory frameworks for combined products. **Salvatore Scalzo** explained how the recently proposed horizontal rules on artificial intelligence aim to reconcile several objectives: foster the interplay with existing legislation, create a flexible framework, enable the use of appropriate standardization and facilitate stakeholders' involvement. **Khair ElZarrad** underlined the need to set up an agile framework, able to embrace changes in areas such as evidence generation, digitalization and clinical trial settings. He explained how the FDA is engaging with the community to build this new framework. Anthony

Humphreys affirmed that the EU health policy is at a critical juncture, which creates an opportunity to define an agile framework for combined product, for instance for emerging clinical data generation or via integrated scientific advice and evaluation pathways. **Jack Turner** explained how the United Kingdom is seeking to redefine its framework for medical devices in order to both maintain the country competitiveness and remain aligned with international standards. **Birka Lehmann** emphasized the importance of integrating patients' perspective when designing the regulatory framework for combined products. **Jonathan Sutch** shared his views on key challenges for combined products such as the harmonization of definitions, interactions between manufacturers, medicines agencies and Notified Bodies and the consistency of Notified Body opinions.

During the discussion, the panelists debated how to improve global regulatory alignment. They agreed on the necessity to achieve a certain degree of convergence. The panelists evoked different pathways to ensure that the framework is fit for new technologies, such as the creation of regulatory sandboxes and new ways to engage with stakeholders. The audience was given the opportunity to ask questions and take part in the discussions via several polls. The panelists shared their view on stakeholder collaboration for pre-market activities, progress toward common definitions and risk classification, as well as the opportunities and pitfalls of standardization.

In the afternoon, attendees took part in 4 sessions during which experts presented their experience and shared their view on various topics relevant for combined products. Attendees had the opportunity to interact with them through Q&A sessions.

Session 1 presented complementary perspectives on the framework for combined products in the EU. The speakers shared their perspectives on the impact of the Medical Devices and *In Vitro* Diagnostics Regulations for the development, certification, and authorization of combined products. They touched upon the changes in the interactions between stakeholders, the requirements and challenges of the Notified Body opinion and the interfaces between the existing regulatory framework for medicines, medical devices, *in vitro* diagnostics and clinical trials.

Session 2 addressed the potential of digitalization in healthcare. The speakers presented the impact of the commoditization and consumerization of healthcare on the interactions between stakeholders and the potentials of *in silico* medicine for therapy development. They shared perspectives on the driving role of startups in innovation and provided considerations for a systemic approach to the design of connected combined products.

Session 3 focused on the involvement of patients in the development of combined products. Speakers built on their experience and provided insights on patient training, the integration of user experiences in product development to improve first time use, human behavior design and human based engineering as a tool to enhance product desirability.

Session 4 explored new avenues for the development of combined products. Speakers outlined the challenges and opportunities of cell and gene therapies and shed light on the reduction of manufacturers' carbon footprint. They advocated for a stakeholder-focused approach to innovation as well as to drive regulatory change to support disruptive innovations.

The MPP2021 was a great success and we look forward to welcoming you at next year's edition that will take place in Basel, Switzerland on 8 September 2022.

MEDTECH & PHARMA
PLATFORM

Acknowledgements

We would like to extend special thanks to our sponsors and partners including the Canton of Basel, Capgemini Engineering, MSD, Novartis, Roche, SFL Regulatory Affairs & Scientific Communication, and Ypsomed which support this conference. Thank you to our networking and media partners.

About the MPP Association

The MPP Association is a cross-sectoral not-for-profit industry association focusing on combined products. The Association comprises medtech, pharma and ICT companies dedicated to enhancing the synergies between these industries. The Association aims to achieve a balanced regulatory framework for combined products in Europe, reduce time to market and improve access to innovative and safe healthcare products.

Contact us

Medtech & Pharma Platform
c/o SFL Regulatory Affairs & Scientific Communication GmbH
Aeschenvorstadt 52, CH-4051 Basel, Schweiz
+41 61 361 9443
association@medtech-pharma.com
https://www.medtech-pharma.com/